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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/862,417	05/23/2001	Xiao Bing Wang	122001-1050	8468

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EXAMINER

SIEW, JEFFREY

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 04/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/862,417	<b>Applicant(s)</b> WANG, XIAO BING	
	<b>Examiner</b> Jeffrey Siew	<b>Art Unit</b> 1637	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on int 3/2/03.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4,6 and 11-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4,6 and 11-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### **THE PREVIOUS NOTICE OF ALLOWABILITY IS HEREBY WITHDRAWN IN LIGHT OF NEW PRIOR ART REJECTIONS**

#### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Claims 1-4,11-15,18,20-28,38,42,43,46 & 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Prezant et al (Human Mutation vol. 1: 159-164 1992).

Prezant et al teach a method of detecting target nucleic acid by preparing at least one primer matched to predetermined position of target nucleic acid, annealing one primer to target to obtain primer nucleic acid duplex, mixing duplex with non terminator mixture where at least one of A,T,G or C is omitted and one non terminator nucleotide of the non terminator nucleotide mixture which is not omitted is labeled with detectable marker, performing isometric extension and detection. (see whole doc. esp. abstract- teaching detecting point mutation using a biotinylated oligonucleotide on an amplified DNA template using single nucleotide incorporation using Taq thermostable DNA polymerase with radioactive dNTP). They teach detecting point mutation in hemoglobin (see page 160).

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 31-37,39 & 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prezant et al (Human Mutation vol. 1: 159-164 1992) in view of Monforte et al (US5,700,642 Dec. 23, 1997).

The teachings of Prezant et al are described previously.

Prezant et al do not teach primer immobilization on support.

Monforte et al teach modified oligonucleotides primers designed for attachment to solid support and extension (see whole doc. esp. abstract). They also teach photocleavable linkers (seecol.24 line 60-62).

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One of ordinary skill in the art would have been motivated to apply Monforte et al's immobilized primers to Prezant et al's method of detection in order to efficiently separate and detect extended products. Monforte et al states that immobilized primers allow for easy detection and separation that avoid the multiple handling steps of washing and gel separation (see col.3 line 50-55). It would have been prima facie obvious to apply Monforte et al's immobilized primers to Prezant et al's detection method in order to quickly separate extended product for detection.

3. Claims 29 & 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prezant et al (Human Mutation vol. 1: 159-164 1992) in view of Ruth (US4,948,882 Aug. 14, 1990).

The teachings of Prezant et al are described previously.

Prezant et al do not teach chemical or non-enzymatic synthesis of target from support.

Ruth teach non-enzymatic synthesis of nucleic acids (see whole doc. esp. abstract).

One of ordinary skill in the art would have been motivated to apply Ruth's method of synthesis of target nucleic acids to Prezant et al's detection method in order construct nucleic acid target with specific modifications. Ruth states that non-enzymatic synthesis allows for synthesis of nucleic acids with preselected sequence and length with modified nucleotides capable of detection (see col.3 line 46-52). It would have prima facie obvious to apply Ruth et al's synthesis method to Prezant et al's detection method in order to create specific targets of desired length and sequence.

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4. Claims 16, 17 & 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prezant et al (Human Mutation vol. 1: 159-164 1992) in view of (Schuster et al US5,578,467 Nov. 26, 1996).

The teachings of Prezant et al are described previously.

Prezant et al do not teach deoxyinosine.

Schuster et al teach deoxyinosine containing primers for amplification of target nucleic acids (see whole doc. esp. abstract). They teach detecting bacterial and viral samples (seecol.7 line 4).

One of ordinary skill in the art would have been motivated to apply Schuster et al's deoxyinosine primers in Prezant et al's method of detection in order to increase the efficiency of amplification of target. Schuster et al state that deoxyinosine primers equalize the efficiency that both primers in PCR hybridize to target thereby increasing the efficiency of the amplification (see abstract). One of ordinary skill in the art would have been motivated to apply Schuster et al's deoxyinosine primers to Prezant et al's target amplification in order to increase the efficiency of the amplification.

5. Claims 41 & 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prezant et al (Human Mutation vol. 1: 159-164 1992) in view of (Schuster et al US5,578,467 Nov. 26, 1996).

The teachings of Prezant et al are described previously.

Prezant et al do not teach fluorescent dye and electrophoresis or UV detection.

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Mansfield et al teach single nucleotide primer extension with a fluorescent nucleotide and capillary electrophoresis and laser induced detection.

One of ordinary skill in the art would have been motivated to apply Mansfield et al's capillary electrophoresis and laser induced detection to Prezant et al's method of detection in order eliminate the hazards of radioactive detection. It was well known and commonly practiced in the art to use fluorescent labeling to eliminate radioactive detection and provide for increased efficiency of detection. Moreover, it was well known and commonly practiced in the art to use capillary electrophoresis to provide increased size separation of targets. It would have been prima facie obvious to apply Mansfield et al's teaching of fluorescence labels and capillary electrophoresis to Prezant et al's method of detection in order to provide for increased detection and size separation of targets.

## **SUMMARY**

6. Claim 6 is objected for depending on rejected claim but free of the prior art. There is no prior art that teach or suggest the method with the claimed non terminator mixtures. Prezant et al teach using non terminator mix but only one labeled non terminator nucleotide is present.


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### CONCLUSION

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Siew who can be reached at 571-272-0787. The e-mail address is Jeffrey.Siew@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can best be reached on weekdays from 6:30 a.m. to 3 p.m. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571)272-0782.

Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Tracey Johnson for Art Unit 1637 whose telephone number is (571)272-0534.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center FAX is (703)-872-9306.

  
JEFFREY SIEW  
PRIMARY EXAMINER

March 30, 2004